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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,371	05/16/2001	Alison Davies	DAV 13002REF	9780

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Alexandria, VA 22314-1176

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/831,371

## Applicant(s)

DAVIES, ALISON

## Examiner

G. R. Ewoldt, Ph.D.

## Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004 and 02 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2,4-9,11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4-9,11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 2 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendment and remarks, filed 7/02/04 and 9/02/04, are acknowledged. In view of Applicant's amendment and remarks, all previous rejections have been withdrawn. In particular, Applicant's arguments that the prior art teaches away from the transplantation of mature lymphocytes has been found persuasive.

2. Claims 2, 4-9, 11, and 13-16 are pending and being acted upon.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2 and 4-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,575,795.

The '795 patent teaches a method of autologous transplantation of healthy mature lymphocytes (which would include T lymphocytes) obtained from a mature non-diseased human's blood, said cells having been harvested before the suggestion or suspicion of a disease (see column 1, lines 49-60).

The reference clearly anticipates the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,575,795 in view of U.S. Patent No. 5,876,321.

The '795 patent has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach a method further comprising freezing the lymphocytes and using them in cancer therapy.

The '321 patent teaches the freezing of autologous white blood cells (which would comprise dormant lymphocytes) for later use in the treatment of cancer, and the advantages of the use of autologous cells, most specifically, safety (see particularly column 1, lines 48-64).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of autologous transplantation of healthy mature lymphocytes (which would include T lymphocytes) obtained from a mature non-diseased human's blood, said cells having been harvested before the suggestion or suspicion of a disease, as taught by the '795 patent, wherein said cells had been frozen for later use in the treatment of cancer, as taught by the '321 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to prepare and store said cells for the later treatment of cancer given the teachings of the '321 patent that it is safer to use autologous cells in cancer treatment.

7. Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,575,795 in view of Abe et al. (1996)

The '795 patent has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach a method further comprising the use of genetically modified lymphocytes or the use of said cells in cancer therapy.

Abe et al. teaches the use of genetically modified lymphocytes in cancer therapy and that said cells have improved antitumor activity (see particularly page 165, Results).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of autologous transplantation of healthy mature lymphocytes obtained from a mature non-diseased human's blood, said cells having been harvested before the suggestion or suspicion of a disease as taught by the '795 patent, wherein said cells had been genetically modified for use in cancer therapy, as taught by Abe et al. One of ordinary skill in the art at the

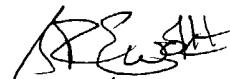
time the invention was made would have been motivated to prepare, genetically modify, and store said cells for the later treatment of cancer, given the teachings of Abe et al. that said cells have improved antitumor activity.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600

  
11/8/04

**G.R. EWOLDT, PH.D.  
PRIMARY EXAMINER**